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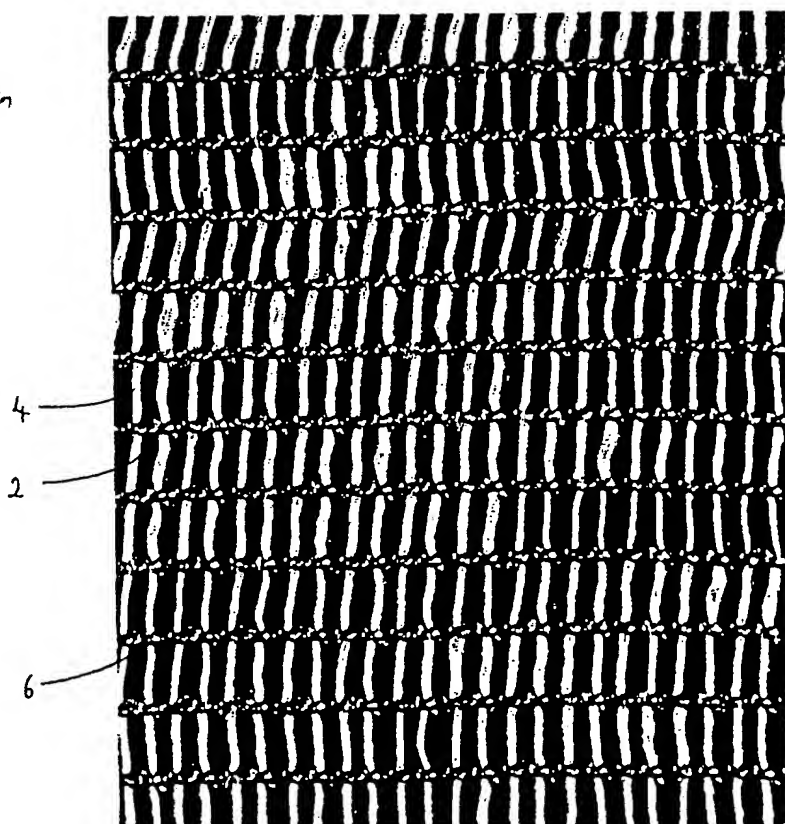
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<p>(21) International Application Number: PCT/EP97/01881 (22) International Filing Date: 11 April 1997 (11.04.97) (71) Applicant (for all designated States except US): BRISTOL-MYERS SQUIBB COMPANY [US/US]; 345 Park Avenue, New York, NY 10154 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): COURT, Andrew, D. [GB/GB]; 72 Greenfields Drive, Little Neston, South Wirral L64 0LU (GB). MAHONEY, Peter, M., J. [GB/GB]; Lletty Meirch Farm, Llanfihangel-Ng-Nhwynfa, Nr. Llanfyllin, Powys SY22 5JF (GB). LYDON, Michael, James [GB/GB]; Tennant Farm, The Vownog, Sychdyn, Mold, Flintshire CH7 6EW (GB). (74) Agent: MAYS, Julie; Bristol-Myers Company Limited, Patent Dept., Swakeleys House, Milton Road, Ickenham, Uxbridge UB10 8NS (GB).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.</p>
<p>(54) Title: KNITTED WOUND DRESSINGS AND METHOD FOR MAKING SAME</p> <p>(57) Abstract</p> <p>The present invention provides a wound dressing comprising a mixture of textile fibres and gel forming fibres chibser, wherein the dressing is a knitted fabric comprising support yarn and in-laid yarn, the support yarn being substantially free of gel-forming fibres.</p> 		

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5 KNITTED WOUND DRESSINGS AND A METHOD FOR MAKING SAME

The invention relates to knitted wound dressings and particularly to wound dressings comprising a mixture of
10 textile fibres and gel-forming fibres and a method for making same.

The invention also relates to a method of treating a wound comprising applying the dressing to a wound.

15

It is well known that the cleansing and debriding of wounds and the removal of wound exudate is important to the process of healing wounds. Commonly used wound dressings
comprise gauze, foams, sponges, cotton wads or other
20 fibrous materials. Gauze and other fibrous materials absorb fluids by capillary action with the disadvantage that when new tissue is formed as part of the healing process, it engulfs the fibres and is torn when the material is removed causing wound injury.

25

There thus exists a need for a dressing which is non-adherent while being absorbent.

PCT WO 95/91795 to Bristol-Myers Squibb Company describes
30 a wound dressing comprising a mixture of textile fibres and gel-forming fibres to form an inexpensive, non-adherent dressing. The dressings disclosed are non-woven structures, the fibres being carded together to form a felt. Non woven fabrics generally have less tensile strength in both wet

5 and dry states than woven fabrics. It is desirable for
wound dressings to have a sufficiently high tensile
strength that they may be handled during processing and
packaging and be removable from a wound in a wet state, in
one piece. For this reason woven fabrics are desirable as
10 wound dressings. In addition a woven structure broadens
the type of fibre that can be used in dressings.

In the past it has been difficult to produce knitted
fabrics comprising gel-forming fibres because of the
15 brittleness of the fibres. Their brittleness can lead to
breakage and shedding of the gel-forming fibres during
processing which not only limits machine speeds but is also
undesirable in a product that is in direct contact with a
wound.

20 We have now found that it is possible to make knitted wound
dressings from a mixture of gel-forming fibres and textile
fibres.

25 Accordingly the present invention provides a wound dressing
comprising a mixture of textile fibres and gel-forming
fibres wherein the dressing is a knitted fabric comprising
support yarn and in-laid yarn, the support yarn being
substantially free of gel-forming fibres.

30 The wound dressing according to the invention may have the
advantage that fast knitting speeds are possible in the
production of the dressing and the resulting product has
better integrity than a dressing where gel-forming fibres

5 are included in the support yarn.

The dressings may also have the advantage that because they are produced by knitting, the final product has good dimensional stability without the choice of fibre being
10 unduly limited.

In the context of the present invention by yarn is meant a continuous strand of textile or staple fibers, filaments or other material in a form suitable for knitting. By staple
15 yarn is meant a yarn composed of staple fibers held together by some binding mechanism such as twisting. By knitting is meant warp, weft or ring knitting.

Preferably the wound dressing is a warp knitted fabric. By
20 warp knitting is meant a knit characterised by the fact that each warp yarn is more or less in line with the direction in which the fabric is produced. The warp yarn forms a support structure of pillars or chains of stitches and for this reason is also known as structural or pillar
25 yarn. The pillars of stitches are held together by a further structural yarn and/or an in-laid yarn which is more or less perpendicular to the direction in which the fabric is produced. Examples of warp knitted fabrics are tricots, raschels, nets and laces such as are described in
30 "Textile Science" by Kathryn L. Hatch, West Publishing Company 1993.

The knitted dressing preferably comprises from 5% to 95% of textile fibres by total weight of the dressing and from 5%

5 to 95% of gel-forming fibres by total weight of the dressing. More preferably the dressing comprises from 15% to 70% by weight of gel-forming fibres and more particularly 20% to 60% by weight.

10 The textile fibres for use in the present invention can be natural or synthetic but are preferably cellulosic fibres for example viscose rayon, multi-limbed viscose, cotton, or regenerated cellulose or fibres having a higher absorbency than most textile fibres such as the multi-limbed cellulose
15 fibres as described in EP-A-301874. In general textile fibres absorb liquids by capillary action and are not hygroscopic. This means that their absorbancies as measured by the free swell absorbancy test are low such as less than 1 gram of liquid per gram of fibre.

20 The gel-forming fibres for use in the present invention are hygroscopic fibres which upon the uptake of wound exudate become moist and slippery or gelatinous and thus reduce the tendency for the surrounding fibres to adhere to the wound.

25 The gel-forming fibres may also swell and separate the textile fibres from the wound surface. The gel-forming fibres can be of the type which retain their structural integrity on absorption of exudate or can be of the type which lose their fibrous form and become a structureless gel or a solution on absorption of exudate.
30

The gel-forming fibres are preferably sodium carboxymethylcellulose fibres, chemically modified cellulosic fibres, in particular carboxymethylated

5 cellulose fibres as described in PCT WO/9312275, pectin
fibres, alginate fibres, fibres made from a composite of
alginate and another polysaccharide, chitosan fibres,
hyaluronic acid fibres, or other polysaccharide fibres or
fibres derived from gums. In particular the alginate
10 fibres described in EP-A-0721355 to Bristol-Myers Squibb
Company are particularly preferred. The cellulosic fibres
preferably have a degree of substitution of at least 0.05
carboxymethyl groups per glucose unit. The gel-forming
fibres preferably have an absorbency of at least 2 grams
15 0.9% saline solution per gram of fibre (as measured by the
free swell absorbency test) and a tenacity of at least
10cN/tex. The production of solvent-spun cellulose fibres
is described for example in US-A-4246221 and US-A-4196281
as well as in PCT WO/9312275. The gel-forming fibres for
20 use in dressings of the present invention may also be
composite or co-spun gel-forming fibres as described in our
co-pending applications GB9607600.5 and GB9618658.0 which
describe fibres that are composites of alginate and another
polysaccharide or those described in PCT WO 96/10106 to
25 Innovative Technologies Limited.

Preferably the gel-forming fibres for use in the present
invention have an absorbency of at least 15 g/g as measured
in the free swell absorbency method, more preferably
30 between 25 g/g and 50 g/g.

The gel-forming fibres suitable for use in the present
invention can be processed using conventional textile
machinery, for example by the staple route including

5 cutting, carding and if desired crimping, drafting and spinning.

The wound dressing of the present invention may be made by spinning or twisting gel-forming fibres and textile fibres
10 together to form the in-laid yarn and then warp knitting using a yarn consisting of textile fibres as the pillar yarn to form a gauze, bandage or stocking. The wound dressing of the present invention may be used as a primary or secondary dressing especially in the treatment of leg
15 ulcers.

The in-laid yarn may be a staple yarn comprising from 0% to 80% by weight of textile fibre and 20% to 100% of gel-forming fibre, more preferably from 0% to 75% by weight of
20 textile fibre and 25% to 100% of gel-forming fibre. Alternatively the in-laid yarn may be a continuous filament yarn comprising from 20% to 100% of gel-forming fibres.

The support yarn is preferably a continuous filament
25 viscose, polypropylene, polyester, polyamide or polyethylene yarn or mixture thereof.

The wound dressing of the invention preferably comprises from 5% to 80% by weight of support yarn and from 20% to
30 95% by weight of in-laid yarn. More preferably from 5% to 60% of support yarn and from 40% to 95% of in-laid yarn.

Various optional ingredients can also be included in the final composition such as preservatives and small amounts

5 of pharmacologically active ingredients. For example an
antibiotic or antimicrobial agent such as metronidazole,
silver sulphadiazine, neomycin or penicillin and antiseptic
agent such as povidone iodine and antiinflammatory agent
such as hydrocortisone or triamcinolone acetonide or a skin
10 protective agent such as a zinc oxide can be included.

These ingredients can be added to the fibres during
production or coated on the fibres, screen printed or spray
coated on the dressing.

15

Preferred embodiments of the invention are illustrated in
the accompanying drawings in which:

Figure 1 is a photograph on an enlarged scale of a first
20 embodiment of a wound dressing according to the invention.

Figure 2 is a photograph on an enlarged scale of a further
embodiment of a wound dressing according to the invention.

25 Figure 3 is a schematic drawing showing the knitted
structure of the wound dressing shown in Figure 1.

Figure 4 is a schematic drawing showing the knitted
structure of the wound dressing shown in Figure 2.

30

Figure 1 shows a wound dressing according to the invention
where the dressing is a knitted fabric comprising support
yarn (2) and in-laid yarn (4), the support yarn (2) being
substantially free of gel-forming fibres. The knitted

5 fabric is a warp knitted fabric meaning that each warp yarn (6) is more or less in line with the direction in which the fabric was produced. The warp yarn (6) is in the form of pillars or chains of stitches held together by the in-laid yarn (4).

10

Figure 2 shows a similar dressing to Figure 1 excepting that in Figure 2 the in-laid yarn (4) is knitted as a double strand. This enables the proportion of gel-forming fibres present in the final dressing to be increased while using the same in-laid yarn. Figures 3 and 4 show schematically and on an enlarged scale the precise structure of preferred embodiments of the invention.

15

20 The invention is further illustrated by the following examples:-

Example 1

25 A wound dressing according to the invention was made as follows. A staple yarn to form the in-laid yarn of a warp knit was made from gelling fibres and textile fibres in the following way. A mixture of an alginate gelling fibre produced as described in EP-A-0721355 to Bristol-Myers Squibb Company (and as used in the product KALTOGEL ex
30 ConvaTec) (20kg) and polypropylene (20kg) (all 3 denier) was cut to a staple length of 40mm and converted into a lap of approximately 100gsm on a conventional short staple scutching line - a Truteschler Opening line. The line

5 comprised a feed table, coarse fibre opener, volumetric feeder, fine opener and lap former.

10 The lap once formed was fed into a worsted type carding machine - a Thibeauc CA6 comprising a weigh pan hopper, fibre opening section and a main carding cylinder. The web of fibres formed was condensed into the form of a sliver with an average weight of 5 grammes per metre length.

15 The slivers were then attenuated on a conventional short-staple draw frame - a Platts Globe Draw Frame - in which rollers operated at differential surface speeds to attenuate the multiple feed of slivers (6-8) into a uniform single sliver of uniform weight and thickness (approximately 3g per metre length).

20 The drawn sliver was converted into roving on a roving frame which further attenuates the sliver. Twist was inserted to add cohesion to the strand. The roving was then spun on a ring spinning machine in which further drafting took place and twist was inserted to form the final yarn.

30 A knitted wound dressing according to the invention was prepared comprising the staple yarn described above as the in-laid yarn and a continuous filament crimped polyester yarn as the support yarn. The dressing was knitted on a crochet knitting machine (Model STP7 ex KOHLER) each needle of which creates a chain of stitches from the support or pillar yarn. The chains are held together by the in-laid

5 yarn. 45 pillar yarn chains were knitted from 150 denier crimped polyester yarn. These were held together by 44 rows of in-laid yarn to form a dressing.

Example 2

10

The dressings as shown in Figures 1 and 2 were warp knitted from an in-laid yarn comprising 35% by weight of alginate fibres as sold in the product Kaltogel ex ConvaTec and 65% by weight viscose fibres ex Lenzing. The support yarn was
15 a continuous filament viscose ex Cellatex. The dressings had the following characteristics.

	Dressing in Figure 1	Dressing in Figure 2
20 Percentage of in-laid yarn by total weight of dressing.	73.6	91.6
Percentage of support yarn by total weight of dressing	26.4	8.4
25 Percentage of textile fibres by total weight of dressing	74.2	67.9
30 Percentage of gelling fibres by total weight of dressing	25.8	32.1

5 Example 3

 An attempt was made to knit a wound dressing on a raschel
knitting machine using a yarn comprising gel-forming fibres
as the support yarn. The support yarn continually broke
and the attempt was abandoned. A wound dressing according
10 to the invention was later knitted by using a support yarn
free of gel-forming fibres.

5

CLAIMS

1. A wound dressing comprising a mixture of textile fibres and gel-forming fibres wherein the dressing is a knitted fabric comprising support yarn and in-laid yarn, the support yarn being substantially free of gel-forming fibres.
2. A wound dressing as claimed in claim 1, the dressing comprising from 5% to 95% by weight of textile fibres and from 5% to 95% by weight of gel-forming fibres
3. A wound dressing as claimed in claim 1 or claim 2 wherein the in-laid yarn is a staple yarn.
4. A wound dressing as claimed in any preceding claim wherein the in-laid yarn comprises from 0% to 80% by weight of textile fibre and 20% to 100% by weight of gel-forming fibre.
5. A wound dressing as claimed in any preceding claim wherein the support yarn is a continuous filament viscose, polyester or polypropylene yarn.
6. A wound dressing as claimed in any preceding claim wherein the fabric comprises from 5% to 80% by weight of support yarn and from 20% to 95% by weight of in-laid yarn.
7. A wound dressing as claimed in any preceding claim

- 5 wherein the fabric is a warp knitted fabric.
8. A wound dressing as claimed in any preceding claim wherein the fabric is a Raschel knitted fabric.
- 10 9. A wound dressing as claimed in any preceding claim wherein the gel forming fibres have an absorbency of at least 2 g/g.
- 15 10. A wound dressing as claimed in any preceding claim wherein the gel forming fibres are hygroscopic fibres which upon the uptake of wound exudate become moist and slippery or gelatinous excepting those composite fibres described in GB9607600.5 and GB9618658.0.
- 20 11. A wound dressing as claimed in any preceding claim wherein the gel forming fibres are sodium carboxymethylcellulose fibres, chemically modified cellulosic fibres, pectin fibres, alginate fibres, fibres made from a composite of alginate and another
- 25 polysaccharide, chitosan fibres, hyaluronic acid fibres, or other polysaccharide fibres or fibres derived from gums excepting those composite fibres described in GB9607600.5 and GB9618658.0.
- 30 12. A wound dressing as claimed in any preceding claim wherein the gel forming fibres are alginate or alginate composite fibres the alginate composite fibres having an alginate content of more than 35% by weight, preferably more than 50% by weight.

5

13. Use of a wound dressing as claimed in any preceding claim for the treatment of a wound by placing the dressing in direct contact with the wound.

10

14. Use of a wound dressing as claimed in claim 1 in the manufacture of a medicament for use in the treatment of wounds.

15

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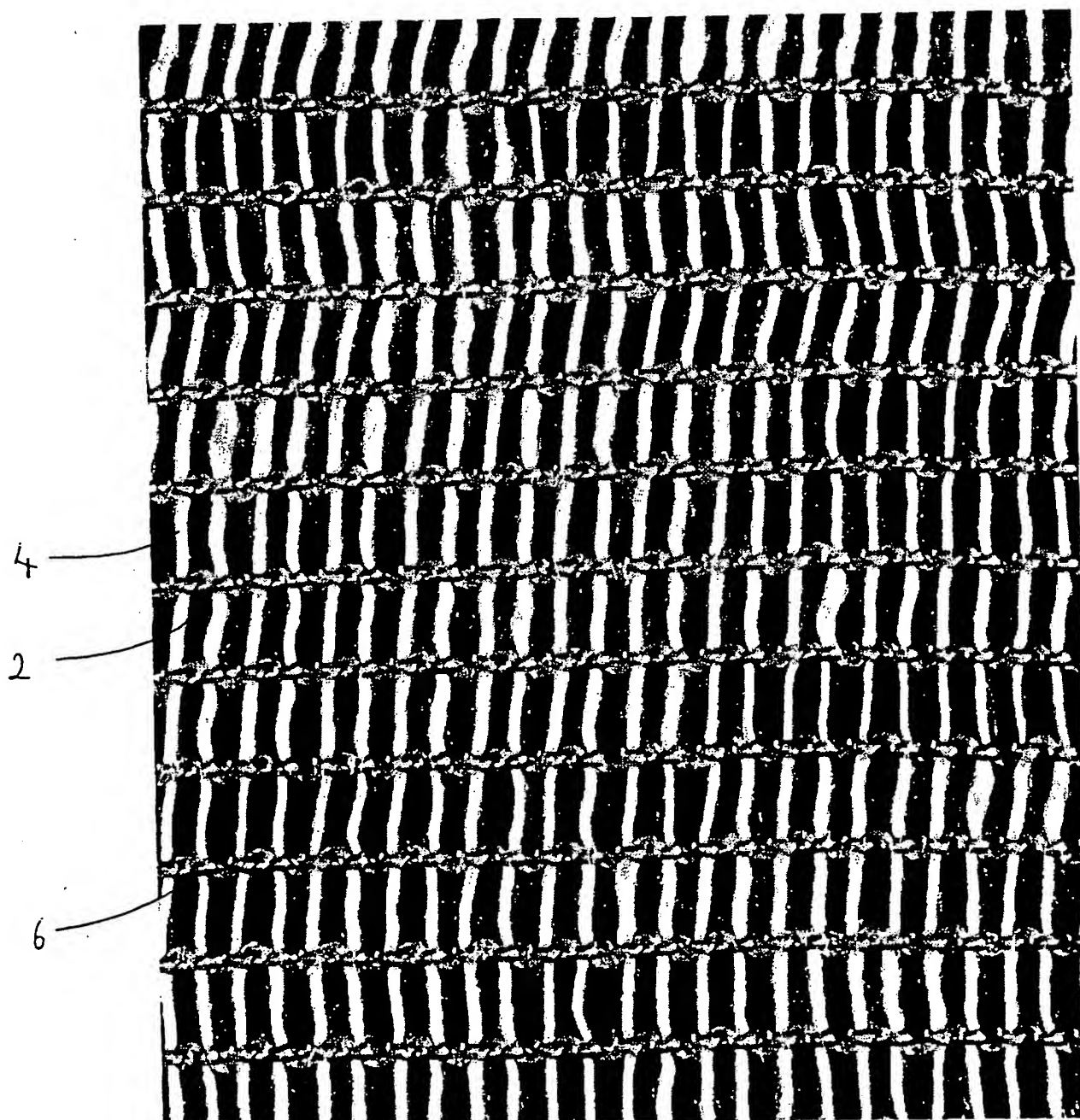


FIG. 1.

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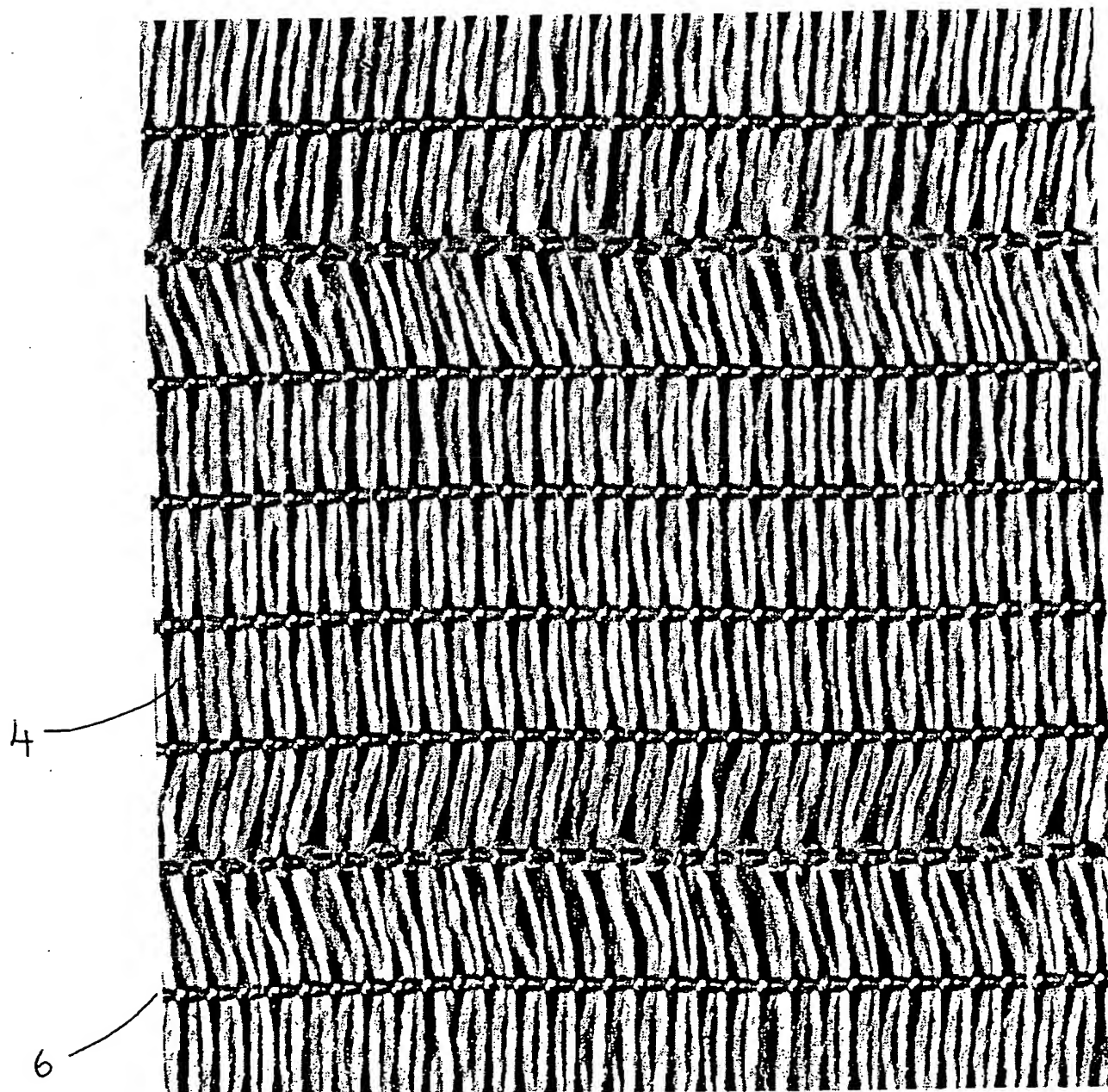


FIG. 2.

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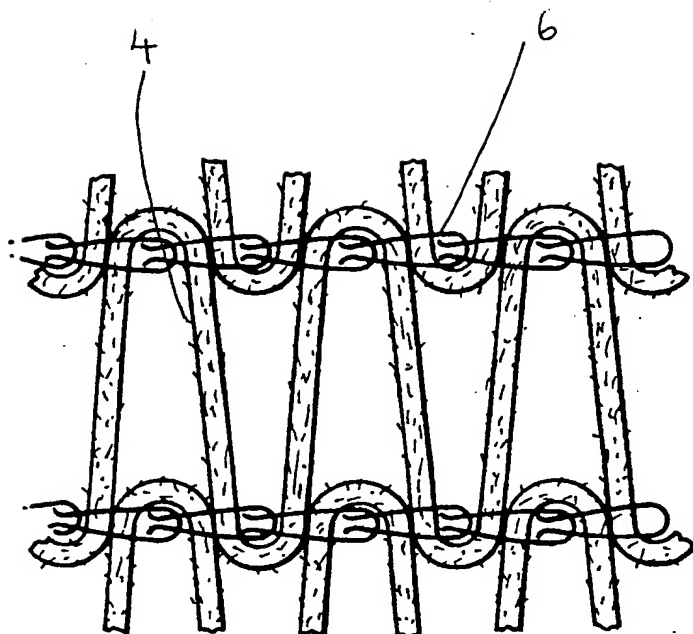


FIG. 3.

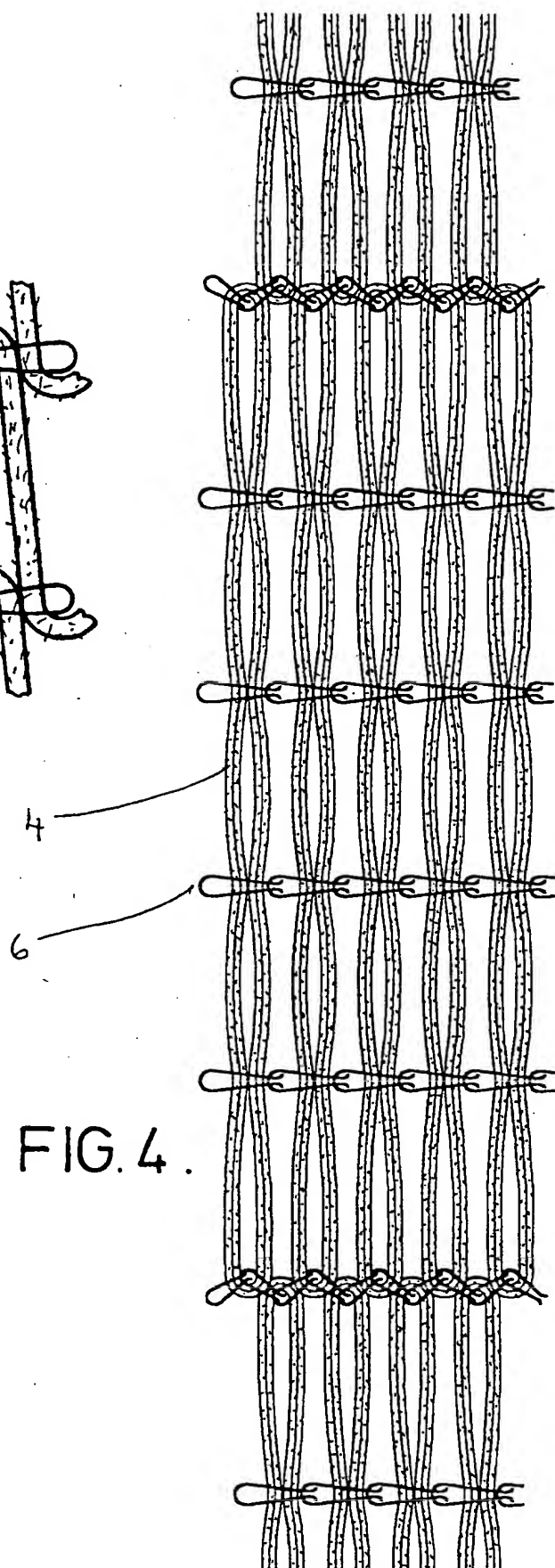


FIG. 4.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 97/01881

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 D04B21/16

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 D04B A61L

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 475 807 A (TERUMO CORP) 18 March 1992 see page 2, line 50 - page 6, line 28	1,7,8, 10-14
A	US 3 645 836 A (TORR DAVID) 29 February 1972 see column 1, line 5 - column 4, line 43	1,2,6-8, 11,13
A	WO 95 19795 A (SQUIBB BRISTOL MYERS CO ;LYDON MICHAEL JAMES (GB); QUEEN DOUGLAS () 27 July 1995 cited in the application see the whole document	1,2,7-14



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0475807 A	18-03-92	JP 4108454 A	09-04-92
		JP 4129561 A	30-04-92
		AU 643058 B	04-11-93
		US 5395305 A	07-03-95
US 3645836 A	29-02-72	DE 1944550 A	26-03-70
		FR 2019407 A	03-07-70
		GB 1286679 A	23-08-72
WO 9519795 A	27-07-95	AU 1667395 A	08-08-95
		CA 2179415 A	27-07-95
		EP 0740554 A	06-11-96
		FI 962916 A	19-07-96
		JP 9509590 T	30-09-97
		NO 962316 A	03-07-96

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